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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/529,205	08/21/2000	Seishi Kato	GIN 6712CPUS	9088

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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	22

DATE MAILED: 10/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/529,205	KATO ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *09 September 2002*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *7-9,13-19,21 and 22*.

10 ☐ Other _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claims 10-12, 20, and 24-25 under 35 USC § 101 and 35 USC § 112, first paragraph (enablement and written description) is withdrawn in view of the cancelled claims.

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 7-9, 13-19, and 21-22 are rejected 35 USC § 101 (utlility) and 35 USC § 112, first paragraph (enablement and written description). Applicant asserts that the Examiner's point concerning the unpredictablility of protein activity from known homologous sequences is not at all well-taken by those of ordinary skill. Applicant indicates that while protein activity can differ markedly upon minor changes, those of ordinary skill nevertheless reasonably expect to find such an activity in homologous peptides. Applicant's arguments have been fully considered but are not found persuasive. Specifically, as discussed in the previous Office Action, Applicant has not provided evidence to indicate that the polynucleotide and polypeptide of the instant application have a specific and substantial asserted utility or a well established utility. Since the specification of the instant application does not disclose any methods or working examples that indicate the polynucleotide and polypeptide of the instant application exhibit similar activities of other proteins, particularly Sca-2, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application. The assertion that the disclosed protein has biological activities similar to Sca-2 is not credible in the absence of supporting evidence, because the relevant literature reports numerous examples of polypeptide families wherein individual members have distinct, and even opposite, biological activities. Additionally, certain positions in the amino acid sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity, and in providing correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions. Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one or ordinary skill in the art to determine, without undue experimentation, the positions in the protein and DNA which are tolerant to change and the nature and extent of changes that can be made in these positions. Furthermore, although Applicant asserts that the polypeptide of the instant application is isolated from tissues of human stomach cancer, there are no methods or working examples that indicate the polypeptide is overexpressed as compared to normal stomach tissue or that the polypeptide is present in any other tissues.

Applicant also asserts that the USPTO recognizes that homology between known and unknown proteins is sufficient to ascribe the known protein's function to the unknown. Applicant indicates that the instant invention most resembles the fact pattern set forth in Example 10 of the "Revised Interim Utility Guidelines Training Materials". Applicant's arguments have been fully considered but are not found persuasive. The polynucleotide sequence in the example has high homology to DNA ligase encoding nucleic acids. In this example, DNA ligases have a well-established utility in the art based on this class of protein's ability to ligate DNA. However, the polynucleotide and polypeptide of the instant application are not supported by a specific and asserted utility or a well established utility although Applicant asserts that the claimed polypeptide of SEQ ID NO: 1 is homologous to the existing Sca-2 protein. Additionally, there is little doubt that, after complete characterization, this DNA and protein, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. Applicant is welcome to submit any evidence in the form of a declaration under 37 C.F.R. 1.132.

Applicant argues that the isolated nucleic acid moleule of SEQ ID NO: 11 and the polypeptide of SEQ ID NO: 1 could be used as research tools to better characterize prior art compounds. Applicant's arguments have been fully considered but are not found persuasive. Since no substantially new arguments have been presented, the rejections are maintained for reasons of record.

[illegible]
PRIMARY EXAMINER